



07/533,294

DAAC

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patentees: Klaus Sommermeyer, Franz Cech, Burghard Weidler, and Klaus Henning

Patent No: 5,218,108 07/533,294

Issued: June 8, 1993

For: HYDROXYLETHYLSTARCH (HES) AS PLASMA EXPANDER AND
PROCESS FOR PREPARING HES

BY HAND DELIVERY

REQUEST FOR INTERIM EXTENSION OF PATENT TERM
UNDER 35 U.S.C. 156(E)(2)

MAIL STOP HATCH-WAXMAN PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The Owner of the referenced patent, Fresenius Kabi, hereby applies for an interim extension of the term for U.S. Patent, 5,218,108, under 35 U.S.C. 156(e)(2). In support of this application, Owner states:

1. U.S. Patent 5,218,108 will expire on June 8, 2010. On February 21, 2008, an application for Patent Term Extension for U.S. Patent 5,218,108 was filed in order to recover lost patent term due to the regulatory review of VOLUVEN® conducted under Section 505(i) and 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (Title 21, United States Code Sections 355(i) and 355(b)(2)). As indicated in the Application for Patent term Extension, the New Drug Application (NDA) for VOLUVEN® was approved on December 27, 2007, under the existing NDA BN070012 to Fresenius Kabi. U.S. Patent 5,218,108 claims pharmaceutical compositions

comprising hydroxyethyl starch, including the sole active ingredient in VOLUVEN® - a 6% hydroxyethyl starch 130/0.4 in 0.9% sodium chloride injection.

2. A Communication dated September 15, 2008, from Mary Till of the Office of Patent Legal Administration indicates that Patent 5,218,108 would be eligible for extension of patent term under 35 U.S.C. 156.

3. No action as yet been taken by the FDA regarding the Application for Patent Term Extension. In particular, no findings regarding the regulatory review period have been made or published yet in the Federal Register notice which allows 180 days for public comments. In view of this, U.S. Patent 5,218,108 will expire before any Certificate of Extension can be issued. Thus, an interim extension under 35 U.S.C. 156(e)(2) is warranted.

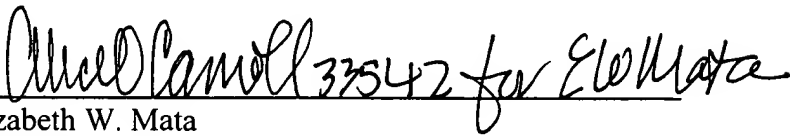
4. It is believed that there are no fees due in connection with this application for interim extension of the patent term. If, however, a fee is due, the Commissioner is hereby authorized to charge the fee(s) to Deposit Account No. 08-0380.

5. If this application for interim extension of the patent term does not comply with the requirements of 35 U.S.C. 156(e)(2), it is requested that the U.S. Patent Office either notify the undersigned so that any necessary corrections can be made, or issue the interim extension on its own accord as authorized under 37 C.F.R. 1.760. The U.S. Patent Office is encouraged to call the undersigned if any issues arise that can be addressed over the telephone.

6. The undersigned thanks Mr. Raul Tamayo of the U.S. Patent and Trademark Office for his continued help regarding the application for Patent Term Extension.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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